

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*,

Plaintiffs,

v.

DALE FOLWELL, *et al.*,

Defendants.

No. 1:19-cv-272-LCB-LPA

**STATE HEALTH PLAN DEFENDANTS' RESPONSE IN OPPOSITION
TO PLAINTIFFS' MOTIONS TO EXCLUDE EXPERT TESTIMONY**

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Rule 702 of the Federal Rules of Evidence *passim*

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I. Introduction

The State Health Plan, Dale Folwell, and Dee Jones (“Plan Defendants”), hereby provide this single Response in Opposition to Plaintiffs’ multiple motions to Exclude expert testimony from Dr. Peter Robie, Dr. Paul W. Hruz, Dr. Paul R. McHugh, Dr. Patrick W. Lappert, and Dr. Stephen B. Levine. Docs. 202-09, 212-13.

Plaintiffs assert these doctors are not qualified to testify as experts; that their testimony is “irrelevant;” and/or that portions of their testimony would be “unreliable” or “patently false.” *See, e.g.*, Doc. 205 at 4-23. In fact, these individuals are highly respected medical professionals with publications and practice experience in relevant fields. Plaintiffs’ attempt to dismiss their qualifications—on the basis of ideological disagreement—misses the mark. Furthermore, opinions regarding the efficacy of certain medical treatments are directly relevant to the Plaintiffs’ allegations of discrimination. Plaintiffs’ criticism of these opinions’ relevance and reliability not only misconstrues the facts but also seeks to usurp the role of the factfinder in weighing the importance and accuracy of those facts. The Plan Defendants ask this Court to deny the Plaintiffs’ Motions to Exclude Expert Testimony.

II. Legal Standard

Rule 702 of the Federal Rules of Evidence provides that “[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to

understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.” Fed. R. Evid. 702. The Supreme Court has held that this requires the district court to determine that “any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *see Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995) (*Daubert* and Fed. R. Evid. 702 superseded *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)).

At the outset, the district court must consider the expert’s qualifications to offer testimony, including his professional record and “full range of experience and training.” *Belk, Inc. v. Meyer Corp.*, 679 F.3d 146, 162 (4th Cir. 2012). But expert testimony may rest on knowledge, skill, experience, training, or education. “These are disjunctive; an expert can qualify to testify on any one of the grounds.” *Cooper v. Laboratory Corp. of America Holdings*, 150 F.3d 376, 380 (4th Cir. 1998) (citing *Kopf v. Skyrn*, 993 F.2d 374, 377 (4th Cir. 1993)). As a result, “although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert.” *U.S. v. Young*, 916 F.3d 368, 381 (4th Cir. 2019) (citing *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017)).

In assessing reliability, the district court may consider (1) whether the expert's reasoning can be tested, (2) whether the expert's reasoning is subject to peer review and publications, (3) the rate of error, and (4) the level of acceptance of the expert's reasoning in the relevant professional community.

Kumho Tire Co. v. Carmichael, 526 U.S. 137, 149-50 (1999); *see Daubert*, 509 U.S. at 593-94. However, the court has "broad latitude" to determine whether these factors are "reasonable measures of reliability in a particular case." *Kumho*, 526 U.S. at 153. The Fourth Circuit has emphasized that Rule 702 liberalizes the presentation of relevant expert testimony, so the reliability analysis need not determine the expert testimony is irrefutable or certainly correct. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). Instead, when expert testimony relies on experiential qualification, the court should consider "how [the expert's] experience leads to the conclusion reached, why [the expert's] experience is a sufficient basis for the opinion, and how [the expert's] experience is reliably applied to the facts." *U.S. v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007).

Under Rule 702, expert testimony is relevant if it has "a valid scientific connection to the pertinent inquiry" and helps "the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591-92. The Fourth Circuit has held that in a case where evidence is "complicated, touching by necessity on a wide variety of ideas, terms, people, and

organizations connected to” the topic at hand, expert testimony is relevant to help the factfinder understand evidence related to the motives of the relevant actors. *U.S. v. Benkahla*, 530 F.3d 300, 309 (4th Cir. 2008).

Significantly, the Supreme Court has instructed district courts, “as gatekeeper, [to] conduct[] a flexible inquiry, focusing on the principles and methodology employed by the expert rather than the conclusions reached.” *Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 690 (W.D.N.C. Apr. 17, 2003) (citing *Daubert*, 509 U.S. at 594-95). After all, a district court’s gatekeeping role “is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule.” *In re Lipitor Mktg.*, 892 F.3d 624, 631 (4th Cir. 2018).

III. Drs. Levine, McHugh, Hruz, Lappert, and Robie are highly qualified to testify as experts.

A. Plaintiffs seek to improperly constrain the scope of “knowledge, skill, experience, training, or education” under Rule 702.

Plaintiffs assert that the challenged experts lack the requisite “knowledge, skill, experience, training, or education,” making their testimony inherently unreliable. Doc. 203 at 8; Doc. 207 at 6; Doc. 213 at 22. Plaintiffs’ claim relies on their view that these experts have limited experience with providing direct medical treatment to transgender patients and publishing “original or peer-reviewed research about gender identity, transgender people,

or gender dysphoria.” Doc. 207 at 6; *see generally* Doc. 203 at 8-10, Doc. 205 at 5-8, Doc. 209 at 6-8, Doc. 213 at 20-22.

But this assertion directly contradicts the Fourth Circuit’s analysis for expert qualification. An expert’s research work is straightforwardly not dispositive: “although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert.” *Young*, 916 F.3d at 381. Similarly, by focusing only on “experience” and “training,” Plaintiffs ignore the Fourth Circuit’s instructions that “an expert can qualify to testify on any one of the grounds.” *Cooper*, 150 F.3d at 380 (emphasis added). Here, the challenged experts’ knowledge, skill, and education—as summarized below—are more than adequate to establish specialized knowledge of the matters at hand.

Furthermore, Plaintiffs rely heavily on the purported principle that “an expert’s qualifications must be within the same technical area as the subject matter of the expert’s testimony,” citing two federal district court decisions from Illinois and a single holding from a different court of appeals. *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362 at *2 (N.D. Ill. Aug. 30, 2007); *see also O’Conner v. Commonwealth Edison*, 807 F.Supp. 1376 (C.D. Ill. 1992); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352 (11th Cir. 2014). These cases are non-binding, of course, but Plaintiffs also

apply them in a misleading way. In claiming the challenged experts are not qualified simply because they have not performed narrowly-defined medical procedures or published in specific journals, Plaintiffs artificially constrain the “technical area” of the substantive issues at hand.

Instead, consistent with the inclusive approach mandated by Rule 702, this Court should recognize that a multitude of medical specialties—including, but not limited to, endocrinology, psychiatry, and plastic surgery—relate to the treatment of transgender individuals. Under this view, the challenged experts clearly have an extensive substantive basis to offer opinions on the relevant factual disputes, as summarized in the following subsections.

1. *Dr. Levine*

Dr. Levine is a licensed physician and, currently, Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. Dr. Levine maintains an active private clinical practice, and he specializes in treatment of sexual identity issues, sexual problems, and the relationship between love, intimacy, and mental health. Dr. Levine first encountered a patient with gender dysphoria in July 1973, and he founded the Case Western Reserve University Gender Identity Clinic in 1974. He still serves as Co-Director of that clinic, having evaluated and treated hundreds of patients with transgender identities. Dr. Levine was an early member of the Harry Benjamin International Gender Dysphoria Association (now known as

WPATH) and served as Chairman of the WPATH committee that developed the fifth edition of the Standards of Care. Dr. Levine is a Distinguished Life Fellow of the American Psychiatric Association and has lectured frequently to professional groups on transgender identity and other issues related to human sexuality. Exhibit 1, Declaration of Dr. Levine.

2. *Dr. McHugh*

Dr. McHugh is a licensed psychiatrist and tenured professor at the Johns Hopkins University School of Medicine. Dr. McHugh was Chairman of Psychiatry at Johns Hopkins Medical School and psychiatrist in chief at the JH Hospitals for 30 years. Dr. McHugh also served as the Chairman of the Medical Board of the entire Johns Hopkins University Hospital. He has published many peer-reviewed articles, books, and chapters in relevant areas including diagnosis, treatment efficacy, and the history of methodological errors in psychiatry. Dr. McHugh was elected to the Institute of Medicine of the National Academies of Science in 1992. Dr. McHugh is also a Distinguished Life Fellow of the American Psychiatric Association. Exhibit 2, Declaration of Dr. McHugh.

3. *Dr. Hruz*

Dr. Hruz is an M.D./Ph.D specialist in pediatric endocrinology at Washington University School of Medicine in St. Louis, Missouri where he also serves as Associate Professor of Cellular Biology and Physiology in the Division

of Biology and Biological Sciences. At this institution, Dr. Hruz served as Chief of the Division of Pediatric Endocrinology and Diabetes from 2012 to 2017 and as Director of the Pediatric Endocrinology Fellowship Program from 2008 to 2016. Dr. Hruz has published sixty scholarly articles over his academic career, including peer-reviewed articles in leading journals on metabolism, cardiology, HIV, and ethics. Dr. Hruz has participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development, and he was a founding member of the school's multidisciplinary Disorders of Sexual Development program. Dr. Hruz has extensively studied the scientific literature related to the incidence, potential etiology, and treatment of gender dysphoria. Exhibit 3, Declaration of Dr. Hruz.

4. *Dr. Lappert*

Dr. Lappert is a licensed physician and, until his recent retirement from surgical practice, a board-certified plastic and reconstructive surgeon. Dr. Lappert has broad experience through his twenty-year career as a flight surgeon with the United States Navy. While serving in uniform, Dr. Lappert was Chairman of the Department of Plastic and Reconstructive Surgery at the Naval Hospital in Portsmouth, Virginia, and Specialty Leader for Plastic and Reconstructive Surgery for the Surgeon General of the Navy. As a physician and surgeon, Dr. Lappert has treated thousands of patients in seven states and four foreign countries. He has personal experience with the surgical

procedures performed as part of sex reassignment surgery, although he performed these surgeries for other purposes (such as reconstruction of the genitals after cancer) rather than for treatment of gender dysphoria. Exhibit 4, Declaration of Dr. Lappert.

5. *Dr. Robie*

Dr. Robie is a licensed primary care physician with more than forty-seven years of clinical experience. Dr. Robie has served as Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine for the Wake Forest School of Medicine since 1981. Exhibit 5, Disclosure of Dr. Robie.

Unlike the other experts for Plan Defendants, Dr. Robie does not seek to provide testimony on the efficacy of gender dysphoria treatment or the lack thereof. As a member of the Plan's Board of Trustees, and as a physician, Dr. Robie has contributed his medical knowledge to Board deliberations. Dr. Robie will testify to the medical knowledge he shared with other Board members. In addition, as an expert in the diagnostic process, he will testify that physicians must know the biological sex of patients to provide competent medical care. Exhibit 5.

B. Plaintiffs seek to exclude the challenged experts based on their conclusions rather than their qualifications and methodology.

Tellingly, Plaintiffs repeatedly suggest that the challenged experts are not qualified to testify because of their unfamiliarity or disagreement with the World Professional Association for Transgender Health’s (“WPATH”) standards of care for transgender individuals. Doc. 203 at 8-9, Doc. 205 at 13-14, Doc. 207 at 6-7, Doc. 209 at 14-15. If adopted, this principle would systematically exclude any testimony presenting an opinion that diverges from Plaintiffs’ desired conclusions. For example, if an expert may not testify unless he or she has provided “gender-affirming surgery,” then no expert with reservations about such procedures could ever be heard by this Court. Under Plaintiffs’ approach, Rule 702 analysis would ask not whether the expert evidence would “assist the trier of fact to understand the evidence or to determine a fact in issue,” but instead whether it would help the jury to adopt Plaintiffs’ understanding of that fact.

This self-serving approach misunderstands the function of Rule 702 and the role of expert testimony. For the reasons outlined below, the lack of consensus among the medical community will play an important role in the factual resolution of Plaintiffs’ equal protection claims. Plaintiffs observe this lack of consensus and conclude that any disagreement with their view of transgender medical treatment is inherently unreliable. But the very

existence of such disagreement highlights the need for the jury to consider the different expert perspectives in its assessment of the motives for Plan Defendants' coverage decisions.

IV. The testimony of Drs. Robie, Hruz, McHugh, Lappert, and Levine speaks directly to dispositive factual questions.

A. *The challenged experts address the medical necessity of Plaintiffs' desired treatments.*

Plaintiffs argue that their enrollment in the State Health Plan entitles them to coverage for all “medically necessary pharmacy benefits, mental health benefits, and medical care such as surgical benefits.” Doc. 75 at 15. This is a faulty assumption, because medical necessity informs, but does not dictate, the Plan’s coverage decisions. *See* Doc. 197 at 31-34. Regardless, Plaintiffs seek damages and injunctive relief for the denial of “medically necessary hormone therapy or gender-confirming surgical care,” Doc. 75 at 21, and “medically necessary surgery,” *id.* at 26. Plaintiffs assert “that gender-confirming health care can be medically necessary and even life-saving,” *id.* at 2, to support their conclusion that the Plan discriminates by “categorically excluding all coverage for [this] medically necessary” treatment, *id.* at 37.

Accordingly, the medical necessity of Plaintiffs’ desired treatments is a factual question at the core of their requests for relief. If Plaintiffs argue that the Plan necessarily discriminates by excluding coverage for “medically necessary” care, they must establish that the specific surgery and hormone

therapy they seek is medically necessary. Sweeping assertions about the “life-saving” value of these treatments, and conclusory reliance on the WPATH standards (which are now 10 years old and increasingly controversial), present only one perspective on this factual question, which the factfinder need not necessarily credit. The challenged expert testimony provides scientific information that will be essential to the jury’s ultimate determination whether the Plaintiffs’ desired treatments are “medically necessary.” Thus, these experts will help “the trier of fact to understand the evidence or to determine a fact in issue,” and their testimony is relevant and admissible pursuant to Rule 702 and *Daubert*, 509 U.S. at 591-92.

B. The challenged experts address the motives for the Plan Defendants’ coverage decisions.

Plaintiffs seek to establish discrimination by claiming that “denying coverage for such health care necessarily discriminates against transgender people.” Doc. 75 at 15. Plaintiffs also allege, however, that “NCSHP’s actual motivations matter to the analysis” and present Plan policy documents and public statements. Doc. 179 at 26. In particular, Treasurer Folwell’s most prominent statement regarding the Plan’s coverage decision specifically points to “the legal and medical uncertainty of this elective, non-emergency procedure.” Exhibit 6, Statement of the Treasurer. Accordingly, Plaintiffs’ discrimination claims hinge in large part on whether this statement is

accurate. If there is “medical uncertainty” regarding Plaintiffs’ desired procedures, then the Plan has presented a compelling alternative explanation to Plaintiffs’ allegations of discrimination. The Fourth Circuit has held that expert testimony is relevant when it helps the jury to understand motive in scenarios with complex competing factors. *Benkahla*, 530 F.3d at 309. That is the case here.

V. Plaintiffs’ challenges to the reliability of Drs. Robie, Hruz, McHugh, Lappert, and Levine are irrelevant and misleading.

A. *The validity of and scientific basis for the WPATH Standards are matters of considerable dispute that must be resolved by the trier of fact.*

Throughout their filings, Plaintiffs rely extensively upon the WPATH standards referenced above. *See, e.g.*, Doc. 213 at 9-10, 12-13. This reliance highlights a fundamental error in their motions to exclude expert testimony.

As noted by Dr. Levine, who was one of the early members of the organization now called WPATH, “[m]ost psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH” and “[m]any psychiatrists and psychologists who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH.” Ex. 1 at 38. “WPATH represents a self-selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of

others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism nor competent scientific debate and analysis and therefore, deviates from the philosophical core of medical science.” *Id.* at 38-39. Put another way, the WPATH guidelines are not “the product of reliable principles and methods.” Fed. R. Evid. 702(c). WPATH does not qualify as a scientific organization because it allows participation by lay members. Furthermore, the WPATH guidelines are adopted by a voting process, rather than a peer review process, and they do not follow the national guidelines intended to prevent adoption of standards that are tainted by financial conflicts of interest.

In response, Plaintiffs argue that this Court is required to defer to the WPATH guidelines, and accept their validity, as a matter of law. To support this, they most directly rely on *Grimm v. Gloucester County School Board*. 972 F.3d 586 (4th Cir. 2020). The panel opinion in *Grimm* states the WPATH standards “represent the consensus approach of the medical and mental health community” and “have been recognized by various courts, including this one, as the authoritative standards of care.” *Id.* at 595.

These statements have no permissible effect, legal or otherwise, on the evidence before the Court in this proceeding. “Precedents wield authority and power only to the extent that they establish or reinforce a legal rule or principle.” Bryan A. Garner, *et al*, THE LAW OF JUDICIAL PRECEDENT 382

(2016) (emphasis added). It is “clear error” to hold that “stare decisis or res judicata makes a finding of fact applicable to persons not parties to the action in which the finding is made.” *Spector v. United States*, 193 F.2d 1002, 1006 (9th Cir. 1952). *Grimm*, like the other cases Plaintiffs cite, involved factual conclusions. For example, *Grimm* relied upon an amicus brief submitted by medical experts, 972 F.3d at 596; this brief, and any factual evidence in that brief, is not before this Court. *See also* Doc. 205 at 18 (citing to opinion on preliminary injunction in *Brandt v. Rutledge*, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021)).

More fundamentally, this approach to factual questions is antithetical to the Court’s gatekeeping role under *Daubert*. Science should be expected to develop over time. Dr. Levine, one of the Plan Defendants’ experts, summarized as follows:

And I just need to tell you that one of the great advantages of being a professional is that one spends one’s life learning and evolving and changing. And the fact that five years ago or ten years ago, I thought this and today I think this, it may be a problem in the legal profession, but it’s not a problem in the medical profession. We expect doctor’s concepts to evolve with clinical experience in advance of science.

Exhibit 7, Deposition of Dr. Levine at 188:21-189:5. When the U.S. Department of Health and Human Services considered the medical science underlying the treatment of gender dysphoria in 2020, the agency found “there

is, at a minimum, a lack of scientific and medical consensus” to support HHS’s earlier conclusion that the effectiveness of hormone and surgical treatment for gender dysphoria was generally accepted. 85 Fed. Reg. 37187 (June 19, 2020).

Plaintiffs ask this Court to prejudge the scientific evidence by finding that the Plan Defendants’ experts in psychiatry (Drs. Levine and McHugh), endocrinology (Dr. Hruz), and surgery (Dr. Lappert) are not qualified to testify about the methodological flaws and errors in the science and ethics of transitioning treatments because they themselves do not perform these experimental treatments on vulnerable patients. This Court cannot exclude the Plan Defendants’ experts for failure to endorse or practice according to the WPATH guidelines when those guidelines lack scientific reliability, validity, and provide no reliable error rates for safety or efficacy.

B. The scientific justification for Plaintiffs’ desired medical treatments has collapsed in the past three years.

As an initial matter, Plaintiffs misunderstand their burden of proof. The Plan Defendants have been clear and consistent in their explanation for Plan’s decision. Treasurer Folwell stated in 2018 that “[t]he legal and medical uncertainty of this elective, non-emergency procedure has never been greater.”

Ex. 6. *See also* Doc. 75 at ¶ 62.

Plaintiffs argue that the Plan’s failure to cover hormone prescriptions and surgical procedures for treatment of gender dysphoria violates the Equal

Protection Clause. They argue that the Plan’s coverage scheme is inherently discriminatory because the Plan covers certain prescriptions and surgeries (such as mastectomies and breast reconstruction for individuals with cancer) but does not cover the same procedures for treatment of gender dysphoria.

Doc. 179 at 21.

To prevail on an equal protection claim, however, Plaintiffs must also establish that the Plan Defendants have denied a benefit of value. As discussed above, this requires Plaintiffs to demonstrate not only that these denied treatments are medically necessary for them, but also that the treatments are “safe and effective for correcting or ameliorating their gender dysphoria.” *Hennessy-Waller v. Snyder*, 529 F.Supp.3d 1031, 1042 (D. Ariz. 2021) (failure to prove reassignment surgery would be effective in treating gender dysphoria justified denial of motion for preliminary injunction). Unfortunately, the most recent scientific literature—peer-reviewed articles published in respected medical journals—has failed to demonstrate that hormonal and surgical treatments actually improve outcomes for patients suffering from gender dysphoria.

The importance of scientific research can be seen in one specific finding, noted by transgender advocates as well as Plan Defendants’ experts: transgender individuals have high levels of psychiatric morbidity, suicidal acts and completed suicide many years after medical transition. Cecilia Dhejne, *et*

al., Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden, PLOS ONE 2011 6(2): e16885 (2011). Long-term follow up of patients with gender dysphoria who have undergone social and hormonal transition with or without surgical intervention has shown persistent psychological morbidity far above non-transgendered individuals, with suicide attempts seven times and completed suicides nineteen times above the general population even after transition interventions. *Id. See* Ex. 1 at 66-67 (citing Dhejne).

Some advocates argue that these terrible health outcomes indicate the need for the hormonal and surgical interventions that the Plaintiffs seek, but “no reliable-valid scientific studies show that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a “watchful waiting” or a psychotherapeutic model of response.” Ex. 1 at 67. Theories that treatment for gender dysphoria will reduce suicidality are, at this point, only theories. Based on the current state of the science, it is equally possible that the treatments sought by Plaintiffs will create further psychological harm in some patients. No one knows.

In October 2019, the American Journal of Psychiatry published a 10-year follow-up study of thousands of Swedish patients diagnosed with gender dysphoria. Richard Branstrom & John E. Pachankis, *Reduction in Mental*

Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study, AM. J. OF PSYCHIATRY 177(8), 727-34 (2019). Critiques of the article led to a third-party review of its methodology and its correction. The final conclusions, agreed to by the authors and international methodological experts, documented zero benefits to hormone and surgical treatment. Ned H. Kalin, M.D., *Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process*, AM. J. OF PSYCHIATRY 177(8), 764 (2020). Indeed, the raw number of suicides and hospitalizations for mental illness actually increased for transgender patients who underwent transitioning treatments. Agnes Wold, *Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article*, AM. J. OF PSYCHIATRY 177(8), 768 (2020) (noting the data shows “the risk of being hospitalized for a suicide attempt was 2.4 times higher if [the patient] had undergone gender-corrective surgery than if they had not,” although the data set was not large enough to establish a causal relationship).

The findings in the Branstrom article were confirmed in 2021 by a study conducted in the United States. Elizabeth Hisle-Gorman, *et al.*, *Mental Healthcare Utilization of Transgender Youth Before and After Affirming Treatment*, J. OF SEX. MED. 18, 1444–54 (2021). Like the Branstrom study,

the Hisle-Gorman article documented no benefits to gender transition treatments for hundreds of patients followed over many years. “Among 963 transgender and gender-diverse youth using gender-affirming pharmaceuticals, mental healthcare did not significantly change and psychotropic (psychiatric) medications increased following gender-affirming pharmaceutical initiation.” *Id.*

The integrity of the legal process requires that experts be able to discuss and explain these scientific controversies to the jury. If the Plan Defendants’ experts are excluded, Plaintiffs will do what their experts did in their reports: ignore the Branstrom findings and the multiple articles that reach similar conclusions. *See, e.g.*, Haupt, C., Henke, M. et. al., *Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women*, 28 November 2020 (finding “insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition”).

The scientific controversy over the efficacy of hormonal and surgical treatment for gender dysphoria is particularly significant in this case because it undermines the ethical basis for these treatments. The “notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment.” *Cruzan v. Dir., Mo. Dep’t of Health*,

497 U.S. 261, 269 (1990). Informed consent requires the health care provider to “provide the patient with sufficient information about the proposed treatment and its attendant risks to conform to the customary practice of members of the same profession with similar training and experience situated in the same or similar communities.” *Foard v. Jarman*, 387 S.E.2d 162, 164 (N.C. 1990). A “reasonable person” must have a “general understanding of both the treatment or procedure and the usual and most frequent risks and hazards” associated with it. *Id.*

When the risks and benefits of medical treatment are unknown, the treatment is experimental. This does not mean that the procedures or treatments should be prohibited, and the Plaintiffs have not—and cannot—show that the Plan has prohibited anything. The only decision made by the Plan is that it will pay for other treatments, such as counseling, but not the treatments that Plaintiffs desire.

C. Plaintiffs’ motions erroneously assume that gaps in scientific knowledge and differing conclusions are a basis to exclude the Plan Defendants’ experts.

For each of the Plan Defendants’ experts, Plaintiffs seek to identify inconsistencies, other courts that have not agreed with the expert’s testimony, or particular conclusions with which Plaintiffs disagree. These are not appropriate bases to exclude expert testimony, particularly without testimony or cross-examination in a formal *Daubert* hearing.

The Plaintiffs misunderstand the purpose of *Daubert* review. “Whether expert evidence is reliable [and therefore admissible] is primarily a question of the validity of the expert’s methodology, not the quality of the data used or the conclusions produced.” *Krakauer v. Dish Network, L.L.C.*, No. 1:14-cv-333, 2015 WL 5227693, at *5 (M.D.N.C. Sept. 8, 2015) (emphasis added). The Plan Defendants’ conclusions are carefully explained and cited to peer-reviewed articles in extensive reports. None of them should be excluded.

1. *Dr. McHugh*

Dr. McHugh’s expert testimony will expand on the research he has done for more than fifty (50) years to bring medical science—the testing of hypotheses based on biological processes—to the field of psychiatry. Plaintiffs argue that they are entitled to specific procedures to treat their psychiatric diagnoses of gender dysphoria. Dr. McHugh will explain precisely what such a diagnosis means, how the diagnostic categories are created, and why these categories can operate to create harm and prevent thoughtful scientific research. Dr. McHugh offers testimony to help the factfinder understand how the scientific method is applied to research the best treatment for psychiatric illnesses, to provide a framework for the factfinder to understand precisely why the medical treatments for gender dysphoria remain medically uncertain.

Dr. McHugh has testified previously that the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association (DSM) is

“essentially a dictionary based on consensus-seeking voting methodologies rather than evidence-seeking scientific methodologies.” Ex. 2 at 6-7. The DSM is, scientifically, similar to a field guide used by amateur birders to identify birds. *Id.* “It is important for legal professionals to understand that the DSM was created using a consensual, political process of committees and voting methodologies. Voting by committees is not a reliably-valid scientific, evidence-based process. The DSM was thus not built using uniformly valid and reliable scientific processes.” *Id.* “Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever.” *Id.* at 8 (quoting a 2013 statement by Director of the National Institute of Mental Health (NIMH)).

As Dr. McHugh explained in his report, the “unreliability of the DSM assessment process is important to understanding defects in transgender treatment methodologies. Patients who have been diagnosed using the DSM checklist for ‘gender dysphoria’ are diagnosed solely on unverified patient reports.” This is an inherently unreliable process—contrast the blood tests and other objective measures applied to diagnose the various types of heart

disease—indicates an ongoing lack of understanding of how to help these vulnerable, suffering patients. *Id.* at 8-9.

Dr. McHugh has extensive experience, throughout his career, with psychiatric diagnoses (and treatments) that are now widely recognized as harmful to the patients, such as lobotomies and “Repressed Memory Therapy.” *Id.* at 9-10. These failed treatments arose from the same scientifically flawed diagnostic process as the current effort to treat gender dysphoria. Dr. McHugh does not dispute that patients diagnosed with gender dysphoria are suffering, but he has reviewed the scientific literature as it has developed over more than fifty years. Advocates have not produced any rigorous scientific research that proves these treatments will increase the wellbeing of patients. *Id.* at 11-12.

Some of the Plaintiffs’ objections to Dr. McHugh are the generic ones described above, such as their argument that only treating physicians who use the WPATH guidelines—individuals with a clear financial conflict of interest in this case—are qualified to testify about medical treatment of gender dysphoria. Doc. 207 at 6-11. The Plaintiffs then proceed to attack opinions elicited during a deposition that are not within Dr. McHugh’s report. *See, e.g., id.* at 12 (“desistance”), 15-16 (stating, incorrectly, that Dr. McHugh supports “reparative therapy”). These opinions were not offered to this Court, and they do not provide a basis for challenging Dr. McHugh’s methodology.

Plaintiffs also improperly argue that McHugh should be excluded because his views are inconsistent with the cherry-picked reports they cite, or because other courts have relied upon the DSM, Doc. 207 at 21-22, or because he has previously summarized these views in non-scientific journals, *id.* at 22-24. Finally, they argue that Dr. McHugh is biased. All of these may be appropriate arguments to a jury. None of them provide a basis to exclude an expert witness.

2. *Dr. Levine*

The Plaintiffs' objections to Dr. Levine's testimony are similar to those made against Dr. McHugh. Plaintiffs disagree with Dr. Levine's conclusions, but they do not offer meaningful objections to the scientific methodology or experience supporting his views.

Plaintiffs argue that some of Dr. Levine's opinions support their arguments, but this goes to the credibility of the witness, not his methodology. Plaintiffs argue the science underlying the treatment of gender dysphoria is irrelevant because "this is simply an insurance dispute" and the Court "need not resolve questions about the etiology of sex." Doc. 213 at 10. This objection misstates the foundation of Plaintiffs' case. The Plan cannot be constitutionally required to pay for medical treatments that are not proven to actually help the patients. As Dr. Levine will testify, among his other conclusions, that "[t]here are no long-term, peer-reviewed published, credible,

reliable and valid, research studies documenting or establishing:” (1) the “percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria;” (2) the “percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria; (3) the ”reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient”; or (4) the “mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood”. Ex. 1 at 87-88. These conclusions are based on the current scientific literature, and they provide a basis for the jury to conclude that the Plan is justified in its decision not to cover Plaintiffs’ desired medical procedures.

The remainder of Plaintiffs’ objections speak to impeachment rather than any basis for exclusion. Doc. 213 at 13-21. The Plaintiffs no doubt strongly disagree with the conclusions that Dr. Levine has reached, based on the scientific peer-reviewed literature, but this is a basis on which to confront his opinions, not to exclude them entirely.

3. *Dr. Hruz*

Plaintiffs also seek to exclude Dr. Paul Hruz, even though he is the only expert in this case, on either side, who has specialized in the effect of hormones on the human body (*i.e.*, endocrinology). Given that hormone suppression and cross-sex hormones are two treatments that Plaintiffs seek, it is inaccurate to

state that Dr. Hruz lacks relevant scientific knowledge. Doc. 205 at 7-10. He has specifically studied the treatments that Plaintiffs seek. *See, e.g.*, Ex. 3 at 3-4. The fact that Dr. Hruz has concluded that these hormonal treatments are unethical does not render him inherently unqualified. *Id.* at 4-5.

The bulk of Plaintiffs' arguments reflect disagreement with Dr. Hruz's conclusions and statements about the existing scientific literature. Doc. 205 at 9-12. As one example, Plaintiffs argue Dr. Hruz should be excluded because he "has no view about what modality of treatment should be provided to transgender people suffering gender dysphoria." *Id.* at 12. But this is one of Dr. Hruz's key findings: "[d]espite several highly defective research efforts, the Gender Transition Industry has failed to prove long term benefits that outweigh the reported harms, dangers, and serious injuries of 'gender affirmation' interventions." Ex. 3 at 16. The remainder ask this Court to exclude his opinions because they differ from that of other courts, various medical societies, or the Plaintiffs' experts. These are not a proper basis for exclusion. Nor are the Plaintiffs' unsubstantiated claims of bias, which would again be appropriate for cross-examination, but not this Court's analysis pursuant to *Daubert*.

4. *Dr. Lappert*

Plaintiffs' attacks on Dr. Lappert suffer the same flaws. Dr. Lappert has performed every procedure identified by Plaintiffs, but he has not done so for the purpose of treating gender dysphoria. Plaintiffs devote significant attention to Dr. Lappert's decision to retire from the practice of plastic surgery, and the fact that his decision not to renew his board certification was not accurately reflected in his expert report, Doc. 209 at 8-9, but Dr. Lappert did not conceal this accidental error, nor does this provide a basis to exclude his testimony. The remainder of the objections reflect the same attempts by Plaintiffs to ask this Court to defer to professional organizations or to other courts on the facts to be presented in this case. *Daubert* rejected this approach, and the Plaintiffs cannot renew it here. Plaintiffs have presented no valid basis to exclude Dr. Lappert's testimony.

5. *Dr. Robie*

Plaintiffs' motion to exclude Dr. Peter Robie is similarly flawed. Dr. Robie is an accomplished primary care physician in Winston-Salem and the Plan Defendants have been clear about his testimony. He has not prepared an expert report because he will testify about the information he provided to the Plan's board during its discussions. The expert views he has provided beyond this information deal with the diagnostic process followed by primary care physicians and the importance of accurate information about the patient's

biological sex during that process. These views are well within his forty-seven years of medical care and his education.

VI. Conclusion

Accordingly, the State Health Plan Defendants respectfully request that this Court deny Plaintiffs' motions to exclude expert testimony.

Respectfully submitted, this the 23rd day of February, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on the 23rd day of February, 2022, the foregoing was filed electronically with the Clerk of Court using the CM/ECF electronic filing system, which will send notification of such filing to all registered users.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that the State Health Plan Defendants' Response in Opposition to Plaintiffs' Motions to Exclude Expert Testimony (Docs. 202-09, 212-13) complies with the Court's word limit as calculated using the word count feature of the word processing software. Specifically, this singular Response contains less than 6,250 words, including the body of the Response and headings, but not including the caption, signature lines, this certificate, or the certificate of service.

This the 23rd day of February, 2022.

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